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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,318	06/21/2001	James W. Ayres	245-59204	6784

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/887,318	Applicant(s) AYRES, JAMES W.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34,58,73,79,80 and 82-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34,58,73,79,80 and 82-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 19 February 2003.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 16, 17, and 24 under 35 U.S.C. 112 is hereby withdrawn.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 2, 9, 10, 19, 20, 22, 82-84, 86, and 87 under 35 U.S.C. 102(e) as being anticipated by Van Balken *et al.* is hereby withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-34, 58, 59, 63, 73, 79, 80, and 82-87 under 35 U.S.C. 103(a) as being unpatentable over Van Balken *et al.* in view of Wong *et al.* is hereby maintained.

Claims 88-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Balken *et al.* in view of Wong *et al.*

The Van Balken patent teaches oral dosages forms with delayed immediate-release characteristics, in which an active agent is released from a core upon rupture of an outer coating covering the dosage form (See Abstract). The core contains the active agent and common fillers, and binders. Preferably, a small amount of a swellable material, such as cross-linked carboxymethylcellulose is added to this core (See Column 3, Lines 32-45). The coating material may be selected from materials, such as ethylcellulose and other water-insoluble cellulose derivatives, and polymethacrylates (See Column 4, Lines 19-23). The coating material also comprises a water-soluble plasticizer and a brittleness-inducing agent (See Column 3, Lines 58-61; and Column 4, Lines 30-53). The delayed immediate-release dosage form may be also coated with more than one coating materials, and be surrounded with an immediate release formulation (See Column 6, Lines 14-37; and Claim 16). Various release profiles may be achieved with the disclosed dosage form, including one that substantially corresponds to the limitations concerning the active agent release profile of Claim 15 (See Figure 5). Various lag times for the release of the active agent may also be achieved (See Figures 6 and 7).

Van Balken *et al.* do not teach the use of a banded dosage form.

Wong *et al.* teaches a dosage form adapted for retention in the stomach, comprising a polymer matrix and a band of insoluble material that acts to control the swelling of a portion of the polymer matrix, delaying expulsion of the dosage form from the stomach until substantially all of the active agent has been dispensed (See Abstract; Column 5, Lines 10-27; Column 11,

Lines 40-58; and Column 16, Lines 9-27). Polymers suitable for use in the matrix include hydroxypropylmethylcellulose, carboxymethylcellulose, and pectins (See Column 5, Line 55 to Column 6, Line 2). The dosage form is suitable for use with a variety of active agents, including glipizide (See Column 18, Line 33). Alternative embodiments are disclosed, including one formed with an outer layer comprising an active agent (See Column 20, Lines 35-60). Gastric platform dosage forms are included within the scope of the disclosure, including one form in which the matrix is subcoated, banded, and then overcoated (See Column 27, Example 8). The disclosed dosage form dispenses an active agent at a substantially constant rate of release (See Figures 8 and 9)

It would be obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Van Balken *et al.* and Wong *et al.* into the objects of the instant application. The invention of Van Balken *et al.* is directed to a dosage form in which the release of the active agent is delayed for one hour to several hours. The invention of Wong *et al.* features a banded tablet in which expulsion of the dosage form from the stomach is delayed until nearly all of the active agent has been dispensed. Thus, one of ordinary skill would be motivated, with a reasonable expectation of success, to combine the two references in order to create a dosage form that ensures gastric retention for an extended period of time that equals or exceeds the sum of first, the desired lag time of the release of the active agent and second, the time necessary to dispense a substantial portion of the active agent from the core of the dosage form.

Thus, the claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 19 February 2003 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is particularly pertinent with respect to the applicant's arguments regarding Claims 16, 17, 26, 27, and 30-34. It is the position of the examiner that the manipulation of release rates of active substances remains within the purview one of ordinary skill in the art in view of the combined disclosure of the prior art.

The Van Balken *et al.* reference contains a disclosure in which a permeable coating may be obtained in order to give a sustained release profile after a certain lag-time, instead of an immediate- or pulsatile-release profile (See Van Balken *et al.*, Column 5, Lines 8-13). The examiner has given a broad interpretation to this disclosure to mean that in certain instances, the sustained-release of a drug is desirable after a pre-determined lag-time. As such, the examiner has further relied upon the disclosure of Wong *et al.* to provide a method of sustained-release of a drug, which the examiner does not see as being particularly limited solely to the use of a permeable coating, in conjunction with the disclosed dosage form of Van Balken *et al.*, which is covered with a rupturable coating.

Regarding the applicant's assertion that an invention arising from the combined disclosure of the prior art would be inoperable, the examiner disagrees with the applicant's

analysis of what is disclosed by the prior art. Wong *et al.* provide for more than one method by which the disclosed dosage form can be retained in the stomach. The disclosed dosage form may comprise a gastric-emptying delaying agent to facilitate retention in the stomach. Such an agent may be provided, in the view of the examiner, onto the outer surface of the dosage form of the combined disclosure of the prior art (See Wong *et al.*, Column 7, Lines 24-33; and Column 20, Lines 54-60). This is in contrast to the applicant's assertions regarding Claims 3 and 30-34. As another method of facilitating gastric retention, a polymer matrix tube or ring may be provided, the ends of which would flare outwardly, resulting in a larger effective diameter of the dosage form, thereby increasing the gastric retention of the dosage form (See Wong *et al.*, Figures 5, 6, and 7; and Column 7, Lines 53-64). Furthermore, in light of that disclosure and in the view of the examiner, the remnants of a ruptured coating providing a lag-time in the release of a drug, as disclosed in Van Balken *et al.*, would also likely contribute to the gastric retention of a dosage form arising from the combined disclosure of the prior art (See Van Balken *et al.*, Figure 19). Although the Van Balken *et al.* and Wong *et al.* references are directed to differing methods of the differential release of a drug, the applicant has not set forth a convincing argument how such methods are necessarily counteractive to the point where an inoperable species is produced.

Claim 63 has been cancelled. Claims 58 and 59, containing limitations regarding the specific rupturing action of the membrane, are not given patentable weight. What is being ultimately claimed is a composition of matter, not a pattern of behavior by a composition in a particular set of circumstances. The examiner considers the manipulation of a rupturable coating in any particular desired manner to be within the purview of one of ordinary skill in the art. The burden is shifted onto the applicant to show otherwise.

Regarding the applicant's assertions with respect to Claims 11, 12, 23, and 24, it is the position of the examiner that the applicant has not set forth a convincing argument that the limitations set forth therein would be unexpected by one of ordinary skill in the art. In regard to Claim 11, as stated in above, the examiner considers the manipulation of a rupturable coating in any particular desired manner to be within the purview of one of ordinary skill in the art. Limitations drawn to size, shape, and proportion, as embodied in Claims 12, 23, and 24, are not considered to be patentable in view of what has been disclosed in the Wong *et al.* patent (See Wong *et al.*, Figures 4A to 7). The manipulation of size, shape, and proportion in order to control the effective diameter of a dosage form for the purpose of controlling gastric retention is considered by the examiner to have been already established in the prior art. See MPEP § 2144.04.

In response to the applicant's assertions regarding methods of administration of a dosage form in a once-a-day or twice-a-day formulation, the examiner directs the applicant's attention to Wong *et al.*, Column 29, Lines 18-23, in which various technical features and characteristics of the disclosed invention are disclosed, among which are a method of treatment comprising the administration of a dosage form adapted for gastric retention and release of the active agent over a prolonged period. In the view of the examiner, this disclosure, along with the disclosure of the lag-time of the release of the active agent from the dosage form of the Van Balken *et al.* patent being capable of exceeding 6 hours, and the release of the active agent from the dosage form of the Wong *et al.* patent occurring over a period of time approaching 12 hours, makes the methods of administration of a dosage form of the combined disclosures in a once-a-day or twice-a-day formulation obvious. The examiner would also point out that the claim that carries such a

limitation, Claim 14, is written in such a way that the limitation concerning dosing is embodied as one directed to a future intended use of the claimed tablet.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
May 28, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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